

Notice of Allowability

Application No.

09/990,514

Examiner

William T. Leader

Applicant(s)

WILSON ET AL.

Art Unit

1742

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the papers filed on 11 December 2003.
2. ☒ The allowed claim(s) is/are 1-37.
3. ☒ The drawings filed on 21 November 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- * 5. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 2 May 2002
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other See Continuation Sheet.

DETAILED ACTION

1. Applicant's election without traverse of claims 1-37 in the Paper filed on December 11, 2003, is acknowledged.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the Title:

The title has been changed to --Method For Depositing An Enzyme On An Electrically Conductive Substrate--.

In the Claims:

Claims 38-45 have been canceled.

This amendment has been made to bring the title into conformance with the claimed subject matter, and cancels claims directed to the non-elected invention.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Vachon et al patent (6,340,421) is directed to a microelectrogravimetric method for plating an electroactive species such as the enzyme glucose oxidase onto a biosensor. The enzyme solution contains the enzyme, a stabilizing protein, a surfactant and a buffer (column 4, lines 59-62). The concentration of the surfactant is not discussed in terms of critical micelle concentration.

The Anderson patent (6,482,517) is directed to a method of making a coated particle. At column 12, lines 17-31, the critical micelle concentration of a surfactant is described.

The Schultz et al patent (6,242,235) is directed to polymerase stabilization by surfactants. The binding affinity of surfactants for proteins is discussed at column 7, lines 8-49.

The Raguse et al patent (6,342,346) is directed to a method of producing an electrode membrane combination. In co-dispersing a hydrophobic ionophore in aqueous solution, a detergent at levels below the critical micelle concentration may be used (column 5, line 65 - column 6, line 4).

The Johnson patent (5,166,063) was cited by applicant and is directed to immobilization of biomolecules by enhanced electrophoretic precipitation. Johnson teaches that biomolecules may be placed in solution or suspension as colloidal

particles in a liquid including additives such as non-ionic surfactants (column 4, line 65 - column 5, line 6).

4. The following is an examiner's statement of reasons for allowance: Instant claim 1 is written in Jepson form. The improvement in the method of depositing an enzyme onto an electrically conductive substrate as recited in the preamble of the claim comprises the step of adding to the aqueous dispersion from which deposition takes place a surfactant in an amount at least about equal to the critical micelle concentration for the surfactant in the dispersion. As shown by the prior art discussed above, the use of a surfactant in forming a dispersion of an enzyme in a deposition liquid is known in the art. The prior art does not relate the concentration of the surfactant to the critical micelle concentration. Applicant has observed that micelles of the surfactant Triton X-100 are the same size as the GOx molecules and therefore can suppress aggregation of the enzyme and may easily substitute in a pseudolattice formed as the enzyme is deposited (page 15, lines 18-20). The effect of the surfactant Triton X-100 on electrodeposition is illustrated in figure 1. The critical micelle concentration of Triton X-100 is 0.2 mM. Figure 1 shows that the most efficient enzyme deposition occurs above that value. See page 11, line 28 to page 12, line 8 of the specification. The prior art of record does not suggest the use of a surfactant in an amount greater than the critical micelle concentration in the process recited in applicant's claims, and provides no basis for

leading one of ordinary skill in the art to expect the results discussed in applicant's specification and shown in figure 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Oath/Declaration

5. Receipt of the Combined Declaration and Power of Attorney faxed to the PTO on July 12, 2002, is acknowledged. It was not executed in accordance with either 37 CFR 1.66 or 1.68. The signature of Yibai Hu is missing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William T. Leader whose telephone number is 571-272-1245. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays, 7:30-4:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King, can be reached on 571-272-1244. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William Leader
March 3, 2004

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